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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,184	02/12/2001	Howard Sands	12636-898	6040

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/782,184

Applicant(s)

SANDS ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the corr spondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The request for the Extension of Time filed on April 10, 2002 and the IDS filed on March 4, 2002, are acknowledged.

Claims 1-20 are included in the prosecution of this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, 20-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant amended claim 1 to recite 'that are positioned within' an outer layer. What is within the outer layer is one phase, i.e., camptothecin dissolved in the water insoluble and pharmacologically acceptable liquid and not two components separately. The meaning of the use of the term 'are' thus, is unclear.

According to line 6 of claim 18, the camptothecin is dissolved in the liquid; yet line 7 recites "wherein the lipophilic liquid vehicle and the solid particles of the camptothecin are positioned within the outer layer of the given droplet." The later statement means that the compound is in an undissolved state; therefore these two lines are contradictory to each other.

Applicant's arguments with regard to claims 22 and 23 are not found to be persuasive. If the claims recite certain compounds using certain trade terms, it is the applicant's responsibility to find the corresponding chemical names. Furthermore,

second issue with claim 23 is if the lipoid is a specific phospholipid, then the claim should have recited "phospholipid is lipoid". The expression as used presently means that the phospholipid has lipoid in it.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of claims 1-8 and 12-17 under 35 U.S.C. 103(a) as being unpatentable over Haynes (4725442) by itself or in combination with Burke (5552156), is maintained.

Applicant directs the examiner's attention to page 54, line 35- page 56, line 15 and argue that the claimed camptothecin formulations were shown to have surprisingly superior efficacy than other drugs, HYCAMTIN and CAMPTPSAR.

Applicant's arguments to the above rejections have been fully considered, but are not found to be persuasive. These arguments are not found to be persuasive for the reason that it is not a proper comparison. In order to show unexpected results obtained with 9 nitro-camptothecin using the method of invention, one should compare the instant compound with other compounds under identical conditions. That is, the other drugs should be encapsulated in the same way as the claimed compound. Applicant in instant invention compares the claimed compound, which is encapsulated within the phospholipid with commercially available drugs. Haynes essentially teaches the same

claimed composition, which is applicable to any drug. Further, Haynes teaches on col.2, line 46 et seq., that when free drugs are injected, they are eliminated in 'first order' kinetics whereas encapsulated drugs according to his invention, are released in a sustained manner. Based on these teachings, it would appear that what is observed by applicants is what is to be expected and thus it is not unexpected. The rejection is maintained.

Rejection of claims 9-11 and 18-30 under 35 U.S.C. 103(a) as being unpatentable over Haynes (4725442) cited above or in combination with Burke cited above, further in view of WO 99/61001, is maintained.

Applicant has only argued that the instant invention yields unexpected results, which has been addressed above.

Conclusion

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

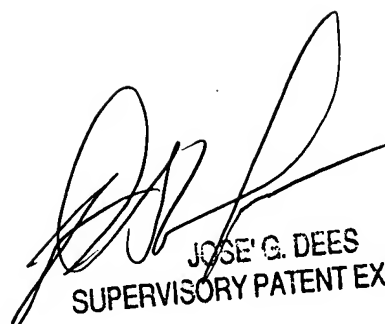
If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

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JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616